

JUL 14 2003

K031724

3.0 510(k) Summary

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Sponsor: Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Contact: Bonnie Smith

Device Name: Synthes Small Combination Clamp – MR Safe

Classification: Class II, 21 CFR 888.3030: "Single/multiple component bone fixation appliances and accessories."

Predicate Device: Imedica's TransFx Small External Fixation System

Device Description: Synthes Small Combination Clamp -MR Safe is a component of an external fixation frame that forms a construct generally intended to treat the hand, wrist, mandible and foot. This device is intended for use in the MR environment. Frame components accept Synthes Ø4.0 mm carbon fiber rods, Synthes Schanz Screws in diameters of 4.0/4.0, 4.0/3.0 and 4.0/2.5 mm and Synthes Ø2.5 mm K-wires.

Intended Use: Intended for fractures of the distal radius, open and/or comminuted or bilateral fractures; fractures in combination with extensive soft tissue injury, bone loss, vascular and/or neural involvement; fractures and dislocations of hand, wrist, mandible and foot; failed closed reduction and casting resulting in secondary deformity of the distal radius.

Materials: Clamps – Stainless steel, titanium alloy and cobalt alloy

Substantial Equivalence Documentation is provided which demonstrates that the Synthes Small Combination Clamp -MR Safe is substantially equivalent* to other legally marketed Synthes devices.

* The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, PA 19301

Re: K031724
Trade/Device Name: Synthes (USA) Small Combination Clamp – MR Safe
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: May 30, 2003
Received: June 3, 2003

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

2.0 Indications for Use Statement

K031724

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510(k) Number (if known): _____

DEVICE NAME: Synthes (USA) Small Combination Clamp – MR Safe

INDICATIONS: Synthes Small Combination Clamps – MR Safe are intended for fractures of the distal radius, open and/or comminuted or bilateral fractures; fractures in combination with extensive soft tissue injury, bone loss, vascular and/or neural involvement; fractures and dislocations of hand, wrist, mandible and foot; failed closed reduction and casting resulting in secondary deformity of the distal radius.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031724

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

Premarket Notification 510(k):
Synthes (USA) Small Combination Clamp – MR Safe

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